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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,091	01/16/2004	Thomas L. Cantor	532212000624	2110

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
01/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/760,091	CANTOR ET AL.	
	Examiner	Art Unit	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-69,71,78-81,83,84,86,92,93,95-107,113,120,127 and 132-147* is/are pending in the application.

4a) Of the above claim(s) *47-68 and 98-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69,71,78-81,83,84,86,92,93,95-97,113,120,127 and 132-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/2009; 12/1/2009; 11/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

2. Applicant's amendment filed on 11/5/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-46, 70, 72-77, 82, 85, 87-91, 94, 108-112, 114-119, 121-126, 128-131, have been cancelled.

Claims 132-147 are added.

Claims 47-68 and 98-107 had been withdrawn. Claims 47-69, 71, 78-81, 83-84, 86, 92-93, 95-107, 113, 120, 127, 132-147 are pending.

Claims 69, 71, 78-81, 83-84, 86, 92-93, 95-97 and 113, 120, 127, 132-147 are under examination.

3. The priority of the instant case is filing date, i.e. 1/16/2004. Although Applicant argues that the parent application 639' and 422' support the instant claimed subject matter. However, Examiner found the arguments not persuasive. Note, the issue on "1-9" PTH fragment has been moot due to the amendment. The only issue is on the "three-dimensional epitope".

Applicant argues that:

> It is known in the art that PTH_{1-8} as part of whole
> PTH contains three dimensional structures or conformations. For example, Fiskin et al., *J. Biol. Chem.,* 252(22):8261-8 (1977) (Exhibit A) analyzed images of parathormone obtained by dark field electron microscopy in order to determine the three-dimensional structure of the molecule. Based on their analysis, Fiskin et al. postulated a model for the PTH three dimensional structure orconformation. *(See* Figure 6 of Fiskin at page 8267, and page 8265, right col.) As shown in the model depicted in Figure 6, the PTH (1-8) amino acid residues as part of whole PTH form an or-helix three dimensional structure or conformation.
>
> The α helix is a rodlike structure. The tightly coiled polypeptide main
> chain forms the inner part of the rod, and the side chains extend

> outward in a helical array (Figures 2-31 and 2-32). The ~ helix is stabilized by hydrogen bonds between the NH and CO groups of the main chain. The CO group of each amino acid is hydrogen bonded to the NH group of the amino acid that is situated four residues ahead in the linear sequence (Figures 2-33). Thus, all the main-chain CO and NH groups are hydrogen bonded. Each residue is related to the next one by a translation of 1.5 A along the helix and a rotation of 100°, which gives 3.6 amino acid residues per turn of helix. Thus, amino acids spaced three and four apart in the linear sequence are spatially quite close to one another in an alpha helix. In contrast, amino acids two apart in the linear sequence are situated on opposite sides of the helix and so are unlikely to make contact. The pitch of the alpha helix is 5.4 A, the product of the translation (1.5 A) and the number of residues per turn (3.6). (Exhibit B., Stryer, at pages 26-27; emphases added.)

Therefore, given that the present application teaches antibodies that specifically bind to an epitope in PTH_{1-8} as part of whole PTH, and at least four amino acids in PTH_{1-8} are part of the reactive portion of the isolated antibody, and given that PTH_{1-8} as part of whole PTH necessarily contains a three dimensional structure, and binding to at least four amino acids in PTH_{1-8} as part of whole PTH necessarily binds to a three-dimensional epitope in PTH_{1-8} as part of whole PTH, it follows that the present application, at least inherently, teaches isolated antibodies that specifically bind to a three-dimensional epitope in PTH~_8 as part of whole PTH, and the present amendments do not introduce any new matter. *See* MPEP § 2163.07(a), citing *In re Reynolds',* 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe,* 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973) (By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.). In addition, because the parent applications have the same or similar disclosures, the presently amended claims are entitled to the filing dates of the parent applications.

Applicant's arguments have been considered, but are not persuasive.

First, as indicated by Applicant, Fiskin et al. "postulated a model for the PTH three dimensional structure". At the time of 1977, the three dimensional model was merely a speculation, i.e. postulated by Fiskin. It is still uncertain whether the fragment is linear or three-dimensional.

Second, the discovered characteristic, such as "three dimensional" epitope, was not disclosed in the specification at the time of filing, it would still be a “new matter” under 35 USC, 112, first paragraph. Note, Examiner hereby does not mean the “three dimensional” per se is a new matter. Rather, the issue is on priority whether the parent 639' or 422' applications render such support. Such term appears in this current application only. The priority should be accorded at the filing date of this application, not back to the priority date of 639' or 422' applications.

Third, if allowing the priority back to the parent case, then most of the applications could incorporate various features or characteristics not disclosed in the specification, but discovered by other inventors/investigators. For instance, take a biomarker protein as an

example. Suppose the claimed invention directs to usage of this biomarker for detection a specific disease. Later, Applicant could incorporate several characteristics of this biomarker protein, such as molecular weight, PI point, certain binding domain in relation to certain drugs....etc.. This would open a flood gates of seemingly "inherency" yet legally "new matter" under 35 USC, first paragraph. Accordingly, the priority of the instant case is on the filing date 1/16/2004.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 132-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the newly amended claims recite at least 5, 6, 7, 8 amino acids in PTH1-8. The specification merely disclose at least four. The "at least four" is a genus, whereas the at least "5, 6, 6, 7, 8" is subgenus.

A subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Broadly articulated rules are particularly inappropriate in this area. Mere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims.

We see an important practical distinction between broad generic chemical compound inventions, for example as in *In re Ruschig*, supra, in which each compound within the genus is a separate embodiment of the invention, and inventions like that at bar, in which the range of solids content is but one of several process parameters. What those skilled in the art would expect from using 34% solids content in the concentrated extract prior to foaming instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homolog of a compound whose properties are disclosed in the specification. We wish to make it clear that we are not creating a rule applicable to all description requirement cases involving ranges. Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. *In re Baird,* 52 CCPA 1747, 348 F.2d 974, 146 USPQ 579 (19965); *In re Draeger*, 32 CCPA 1217, 150 F.2d 572, 66 USPQ 247 (1945).

In particular, no support where found in the specification to picked this particular fragment, i.e. "at least five, six, seven or eight". Therefore, one cannot disclose a forest in the original application and then later pick a tree out of the forest and say here is my invention, the case directing the skilled artisan to that tree must be in the originally filed disclosure. The introduction of claim changes which involve narrowing the claims by introducing a specific core structure for human melterin a which are not supported by the disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

New ground of Rejection

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 69, 71, 78-81, 83-84, 86, 92-93, 95-97 and 113, 120, 127, 132-147 provisionally rejected on the ground of nonstatutory double patenting over claims 1-9, 59, 98-105, 113-114, 139-143 of copending Application No. 10617489. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: both application directs to PTH specific antibody having capability to bind to an N-terminal epitope having 1-8 amino acid residues.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

8. Claims 69, 71, 78-81, 83-84, 86, 92-93, 95-97 and 113, 120, 127, 132-147 are rejected on the ground of nonstatutory double patenting over claims 1-4 of U. S. Patent No. 6689566 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both application directs to PTH specific antibody having capability to bind to an N-terminal epitope having 1-8 amino acid residues.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Primary Examiner, Art Unit 1641